Volume 102
Issue 4 *Dickinson Law Review - Volume 102, 1997-1998*

6-1-1998

Medtronic, Inc. v. Lohr and the Power of Preemption: A Pennsylvania Guide to the Preemption of Common Law Tort Claims by the Medical Device Amendments of 1976

Kenneth J. Witzel

Comments

Medtronic, Inc. v. Lohr and the Power of Preemption: A Pennsylvania Guide to the Preemption of Common Law Tort Claims by the Medical Device Amendments of 1976

"What breaks in me? Some sinew cracks! -'tis whole again . . . ."

-Captain Ahab[1]

I. Introduction

As the number of the elderly steadily increases in the United States,[2] so too does the need for an abundance of reliable, cost-efficient medical devices. Twenty years ago, Congress took a giant step toward ensuring that those devices would be provided when it passed the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act.[3] The MDA were passed in the

1. HERMAN MELVILLE, MOBY DICK 517 (Bantam Classic ed., Bantam Books 1981) (1851).

2. According to the Census Bureau, the growth of the elderly will be steady until 2010; then, during the period between 2010 and 2030, a "massive increase" in the number of the elderly will occur when the Baby Boom generation reaches 65. U.S. BUREAU OF THE CENSUS, CURRENT POPULATION REPORTS, SPECIAL STUDIES, P23-190, 65+ IN THE UNITED STATES 2-5 (1996).

3. *See* H.R. REP. NO. 94-853, at 7-8 (1976); S. REP. NO. 94-33, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071.

wake of growing concern for the safety of medical devices such as the Dalkon Shield.[4] Indeed, the preamble of the MDA states that their purpose is "to provide for the safety and effectiveness of medical devices intended for human use."[5]

The MDA require manufacturers of certain types of medical devices to obtain Food and Drug Administration ("FDA") approval prior to marketing and selling medical devices.[6] To obtain approval from the FDA, manufacturers of these devices must meet the requirements outlined in the FDA regulations.[7]

The MDA also contain a preemption provision, section 360k(a), that prevents states from placing requirements on medical device manufacturers that are "different from" or "in addition to" the regulations promulgated by the FDA.[8] For several years, courts across the country, responding to the United States Supreme Court's decision in *Cipollone v. Liggett Group, Inc.*,[9] have disagreed as to whether the requirements imposed on medical device manufacturers by the MDA preempt state common law products liability claims.[10] In recent years, Pennsylvania courts have held

---

4. The Dalkon Shield was an intrauterine contraceptive device that was introduced to the American public in 1970. The Dalkon Shield was held out by its manufacturers to be safe and effective, but its use resulted in a high percentage of inadvertent pregnancies and several deaths. *See* H.R. REP. NO. 94-853, at 8.

5. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).

6. *See* 21 U.S.C. § 360c(a)(1)(C) (1994). *See also* discussion *infra* note 11.

7. *See* 21 U.S.C. § 360c(a)(1)(C).

8. The MDA preemption provision states:

§ 360k. State and local requirements respecting devices

(a) General Rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included under this chapter.

21 U.S.C. § 360k(a).

9. 505 U.S. 504 (1992). In *Cipollone*, the Court considered federal preemption of state tort claims related to health warning labels on cigarette packages. *See id.* at 508. The Court concluded that the federal statute regulating the labeling of cigarette packages was intended to preempt any additional warning requirements. *See id.* at 517-20. Therefore, the *Cipollone* Court held that certain failure to warn claims presented by the plaintiff were preempted. *See id.* at 524.

10. *See, e.g.,* Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir. 1995) (finding that the MDA preempted all state tort claims against a penile implant manufacturer with the possible exception of an "express warranty" claim); Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995) (finding that the MDA preempted state tort "failure to warn" claims against a

that the MDA preempt state tort claims with regard to devices that the FDA has classified as Class III.[11]

In January 1996, in *Medtronic, Inc. v. Lohr*,[12] the United States Supreme Court addressed several areas of confusion among the lower courts regarding MDA preemption of state tort claims. In so doing, the Court reached two conclusions. First, the *Medtronic* Court refused to hold preempted claims stemming from a defective Class III medical device, a pacemaker that had received its FDA marketing approval through an abbreviated procedure allowable under the MDA.[13] Second, the *Medtronic* Court explained that the MDA will only preempt a state tort claim in cases where the FDA has established "specific counterpart regulations or . . . other specific requirements applicable to the specific device."[14]

This comment considers the past and prospective future of the MDA's preemption provision and the practical ramifications of the Court's decision in *Medtronic*. Specifically, Part II of this comment focuses on the medical device review procedures and the preemp-

---

penile implant manufacturer but not "design defect" claims); Anguiano v. E.I. DuPont de Nemours & Co., Inc., 44 F.3d 806 (9th Cir. 1995) (finding that the MDA did not preempt state tort claims against a manufacturer of teflon used in jaw implants because the FDA did not provide specific requirements regarding teflon); King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993) (finding complete MDA preemption of state tort claims against a Class III device manufacturer); Griffin v. Medtronic, Inc., 840 F. Supp. 396 (D. Md. 1994) (finding that the MDA preempted all state tort claims against the manufacturer of an allegedly defective pacemaker); Elbert v. Howmedica, 841 F. Supp. 327 (D. Haw. 1993) (finding that the MDA did not preempt state tort claims against the manufacturer of an allegedly defective prosthetic knee); Kemp v. Pfizer, Inc., 835 F. Supp. 1015 (E.D. Mich. 1993) (finding that the MDA preempted state tort claims against the manufacturer of an allegedly defective heart valve).

11. The MDA divide medical devices into Class I, Class II, and Class III devices. This comment will only consider those devices classified as Class III devices by the FDA. Class III medical devices are those that the FDA has determined either "present a potential unreasonable risk of illness or injury," are "purported or represented to be for a use in supporting or sustaining human life," or are "for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C).

Class I and II devices may often be marketed without prior approval from the FDA, and, therefore, do not present the same preemption problems as Class III devices. *See* 21 U.S.C. § 360c(a)(1)(A), (B).

For Pennsylvania cases dealing with MDA preemption in Class II medical device cases, see *Riley v. Becton Dickinson Vascular Access, Inc.*, 913 F. Supp. 879 (E.D. Pa. 1995); *Oliver v. Johnson & Johnson*, 863 F. Supp. 251 (W.D. Pa. 1994); *Burgstahler v. AcroMed Corp.*, 670 A.2d 658 (Pa. Super. Ct. 1995).

12. 116 S. Ct. 2240 (1996).

13. *See id.* at 2253-57.

14. *Id.* at 2257 (quoting 21 C.F.R. § 808.1(d) (1995) (FDA regulation)).

tion provision of section 360k of the MDA. Part III considers the trend of Pennsylvania courts following *Cipollone*, yet prior to *Medtronic*. The United States Supreme Court's decision in *Medtronic* is examined in Part IV. In Part V, the effects of the *Medtronic* decision on Pennsylvania courts is discussed. Lastly, Part VI considers the impact of post-*Medtronic* preemption limitations on medical device manufacturers and recipients.

II. MDA Overview

A. Premarket Approval

The MDA require medical device manufacturers to receive a "premarket approval" ("PMA") from the FDA before placing any new Class III medical device[15] on the market.[16] The purpose of the PMA requirement is to give the FDA a method of ensuring that new Class III devices are both safe and effective.[17]

The MDA provide two means by which a Class III device may receive a PMA. The first requires manufacturers to submit detailed information concerning the safety and efficacy of new devices to the FDA.[18] This information then becomes the subject of an FDA panel review, a public meeting, and an FDA advisory committee report and recommendation.[19] The FDA spends an average of 1,200 hours on each submission,[20] and the review process takes a minimum of 180 days.[21]

The second method of receiving a PMA for a Class III medical device is known as the "section 510(k) process," referring to its section number within the MDA. The section 510(k) process applies only to devices that are determined by the FDA to be "substantially equivalent" to pre-MDA devices for which the FDA has not yet completed its PMA review.[22] Section 510(k) allows

---

15. *See supra* note 11 and accompanying text.
16. *See* 21 U.S.C. § 360e(d)(2).
17. *See id.*
18. *See id.*
19. *See* 21 C.F.R. § 814.44(c).
20. *See Hearings Before the Subcomm. on Health and the Env't of the House Comm. on Energy & Commerce*, 100th Cong. 384 (1987).
21. *See* 21 C.F.R. § 814.44.
22. The *Medtronic* Court explained:

> Congress realized that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices. The [MDA] therefore includes a "grandfathering" provision which allows pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates

"substantially equivalent" devices to receive FDA approval through a simplified process.[23] To get approval for a device under the section 510(k) process, a device manufacturer must submit a section 510(k) notification to the FDA.[24] Once the FDA has accepted a device as "substantially equivalent" to an authorized device, the device can be marketed without further regulatory analysis from the FDA.[25]

There are dramatic advantages for manufacturers who are able to receive a PMA for devices through the section 510(k) process. For instance, the FDA spends an average of only twenty hours reviewing each section 510(k) notification it receives, whereas it generally spends 1,200 hours reviewing each standard PMA application under the MDA.[26] One legal commentator explained: "[T]he attraction of substantial equivalence to manufacturers is clear. A [section] 510(k) notification requires [the submission of] little information, rarely elicits a negative response from the FDA, and gets processed very quickly."[27]

On the other hand, the section 510(k) process is not nearly as attractive for consumers of medical devices. While section 510(k) authorization may help keep retail prices for some medical devices down because manufacturers do not incur the expenses associated with fulfilling the standard PMA requirements, section 510(k)-approved devices are not subject to any sort of safety or efficacy review by the FDA. Therefore, recipients of section 510(k)-approved devices do not enjoy any protection from the MDA regarding the safety or efficacy of their devices. If the pre-MDA device is dangerous or ineffective, the MDA provide no assurance that a later device will not also be dangerous or ineffective.[28]

---

and completes the PMA.

Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2247 (1996) (summarizing in part 21 U.S.C. § 360e(b)(1)(A)).

23. *See* 21 U.S.C. § 360e(b)(1)(B).

24. *See id.* § 510(k).

25. *See id.*

26. *See id.*

27. Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 516 (1988).

28. *See* STAFF OF HOUSE SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 98TH CONG., 1ST SESS., REPORT ON MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD 35 (Comm. Print 98-F 1983).

B. MDA Preemption Provision

Also included within the MDA is a specific preemption provision, section 360k.[29] Section 360k has led to questions regarding the degree to which states are able to accommodate common law claims based on medical device defects. In 1991, the United States Supreme Court's decision in *Cipollone v. Liggett Group, Inc.*[30] presented further uncertainties regarding federal regulatory preemption provisions and state common law tort claims. The *Cipollone* decision resulted in numerous federal and state courts holding that most common law products liability claims against medical device manufacturers were strictly preempted by section 360k of the MDA.[31]

III. MDA Preemption of Common Law Tort Claims in Pennsylvania Prior to *Medtronic*

Pennsylvania courts have generally recognized products liability claims arising from manufacturing, designing, and warning defects.[32] Pennsylvania courts recognize claims against these defects under both strict liability[33] and negligence theories.[34]

Following *Cipollone*, the Superior Court of Pennsylvania, in *Green v. Dolsky*,[35] addressed the issue of whether section 360k of the MDA preempts common law products liability claims against device manufacturers of products receiving premarket approval through the *standard PMA process*. The *Green* court concluded that a finding in favor of the Greens on any of their alleged state tort claims would impose "additional or different requirements on [the manufacturer], whose product . . . has already received FDA approval."[36] The court further held that "[s]uch requirements are

---

29. *See* 21 U.S.C. § 360k. *See also supra* note 8 and accompanying text (statutory language).

30. 505 U.S. 504 (1992).

31. *See supra* note 10 and accompanying text.

32. *See* Kenepp v. American Edwards Lab., 859 F. Supp. 809 (E.D. Pa. 1994).

33. Pennsylvania courts have adopted section 402a of the RESTATEMENT (SECOND) OF TORTS (1977). *See* Phillips v. A-Best Prods. Co., 665 A.2d 1167 (Pa. 1995).

34. *See* Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp., 596 A.2d 845 (Pa. Super. Ct. 1991).

35. 641 A.2d 600 (Pa. Super. Ct. 1994).

36. *Id.* at 605.

in conflict with the MDA and thus, the Greens' state law claims are therefore preempted."[37]

Federal courts in Pennsylvania further expanded the preemptive power of section 360k by preempting most state tort claims against manufacturers of products that received premarket approval through the section 510(k) "substantial equivalence" process.[38] This expansion of preemptive power had the effect of providing medical device manufacturers with a protective shield against liability for defective devices even when FDA review of the devices had been cursory. Ironically, the MDA, whose stated purpose is to protect medical device consumers, had become the means of insulating manufacturers against the claims of consumers in Pennsylvania. Pennsylvania courts were not alone in limiting the liabilities of medical device manufacturers through the adoption of an expansive view of section 360k.[39]

IV. *Medtronic, Inc. v. Lohr*

A. Background

In 1987, Lora Lohr was implanted with a pacemaker equipped with a lead that had received its PMA through the section 510(k) process.[40] On December 30, 1990, Lohr's pacemaker failed.[41] Lohr underwent emergency surgery in order to clear a "complete heart blockage" that was allegedly caused by the pacemaker's failure.[42] According to Lohr's doctor, her heart blockage was likely caused by a defect in the pacemaker's lead.[43]

---

37. *Id.*

38. *See* English v. Mentor, 67 F.3d 477 (3d Cir. 1995) (finding all claims preempted except breach of express warranty); Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir. 1995) (finding all claims preempted except breach of express warranty and fraudulent promotion); *In re* Orthopedic Bone Screw Prods. Liab. Litig., No. MDL1014, 1996 WL 221784, at *1 (E.D. Pa. Apr. 8, 1996) (finding all claims preempted except breach of express warranty and fraudulent promotion).

39. In a company press release following the Supreme Court's decision in *Medtronic*, representatives of Medtronic, Inc. "expressed surprise that the Supreme Court had reversed the trend in which the overwhelming majority of lower courts had limited product liability claims for devices that had been cleared for marketing by federal regulatory action." James Cahoy, *U.S. Supreme Court: Medical Device Patients Can Sue in State Courts*, WEST'S LEGAL NEWS, June 27, 1996, *available in* 1996 WL 6272.

40. *See* Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2248 (1996).

41. *See id.*

42. *Id.*

43. *See id.*

In 1993, Lohr filed suit in Florida state court asserting both strict liability and negligence claims against Medtronic, Inc., the manufacturer of the lead.[44] The negligence claim alleged that Medtronic had breached its duty of reasonable care in designing, manufacturing, assembling, and selling the pacemaker.[45] The claim alleged in part that Medtronic had used defective materials in the lead and had also failed to warn Lohr or her physician of the tendency of the pacemaker to fail despite knowledge of other previous failures.[46] The strict liability claim alleged that the device was "in a defective condition and unreasonably dangerous to foreseeable users at the time of its sale."[47]

Medtronic removed the case to federal district court and filed a motion for summary judgment.[48] The district court, following a recent Eleventh Circuit Court of Appeals Decision,[49] granted the motion and dismissed Lohr's claims. On appeal, the Eleventh Circuit Court of Appeals affirmed in part and reversed in part.[50] The court allowed Lohr's claims based on defective design, but held that Lohr's negligent manufacturing and failure to warn claims were preempted by the MDA.[51] Subsequently, Medtronic filed a petition for certiorari seeking the dismissal of the defective design claims.[52] Lohr filed a cross-petition seeking allowance of the defective manufacture and failure to warn claims.[53] The Supreme Court granted both petitions.[54]

---

44. *See id.*

45. *See Medtronic,* 116 S. Ct. at 2248.

46. *See id.*

47. Id.

48. *See id.* at 2248.

49. *Id.* at 2249. The district court had initially dismissed Medtronic's motion for summary judgment, but after the Eleventh Circuit Court of Appeals decided *Duncan v. Iolab, Corp.*, 12 F.3d 194 (11th Cir. 1994), the district court reviewed its previous decision and dismissed the complaint. *See Medtronic*, 116 S. Ct. at 2249.

50. *See* Medtronic, Inc. v. Lohr, 56 F.3d 1335 (11th Cir. 1995).

51. *See id.* at 1347-49, 1351-52. The court of appeals held that the Lohrs' manufacturing claims were preempted by the "good manufacturing practices" requirements of the FDA that establish general guidelines for most steps in every medical device's manufacturing process. *See id.* at 1350. *See also* 21 C.F.R. §§ 820.20-.198 (1995) (FDA regulations establishing manufacturing requirements). The court of appeals held that Lohr's failure to warn claims were preempted by the labeling regulations of the FDA. *See Medtronic*, 56 F.3d at 1350-51. *See also* 21 C.F.R. § 801.109 (FDA regulations establishing labeling requirements).

52. *See Medtronic*, 116 S. Ct. at 2250.

53. *See id.*

54. *See id.*

B. United States Supreme Court's Decision in Medtronic

Although the Justices of the Supreme Court were not able to agree on all the issues presented in *Medtronic*, the Court was able to give significant direction regarding the preemptive powers of the MDA. The decision of the Supreme Court consisted of three opinions. Justice Stevens, joined by Justices Ginsberg, Kennedy, and Souter, wrote the plurality opinion.[55] Justice O'Connor, joined by Chief Justice Rehnquist and Justices Scalia and Thomas, wrote an opinion concurring in part and dissenting in part.[56] Justice Breyer wrote separately concurring in part and concurring in the judgment.[57]

1. 510(k)-approved devices.—The Court found that design defect claims against section 510(k)-approved medical devices are not preempted by section 360k of the MDA.[58] In arriving at this conclusion, Justice Stevens, writing for a majority on this point, held that "[t]here is no suggestion in either the statutory scheme or the legislative history that the section 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents."[59] Stevens added that the "status quo included the possibility that the manufacturer . . . would have to defend itself against state-law claims . . . ."[60]

Justice O'Connor agreed with Justice Stevens that design defect claims for products receiving approval by means of section 510(k) are not preempted "[b]ecause the section 510(k) process . . . places no 'requirements' on a device . . . ."[61] Regardless of the precise reasoning, however, the majority agreed that defective design claims rooted in devices that have received their FDA approval through section 510(k) are not preempted by the MDA.

---

55. *See id.* at 2245.

56. *See id.* at 2262.

57. *See Medtronic*, 116 S. Ct. at 2259.

58. *See id.* at 2254-55, 2264.

59. *Id.* at 2254-55. Justice Stevens further explained that section 510(k) was intended to give manufacturers the "freedom to compete, to a limited degree," with manufacturers of devices existing before 1976. *Id.* at 2254.

60. *Id.* at 2255.

61. *Id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

2. Claims specifically alleging violation of FDA requirements.—Majority support was also garnered for the idea that manufacturing and labeling claims specifically alleging the violation of FDA requirements are not preempted.[62] Justice Stevens relied on FDA regulations[63] in determining that the court of appeals should not have preempted Lohr's manufacturing and warning claims "to the extent that they rest on claims that Medtronic negligently failed to comply with duties 'equal to, or substantially identical to, requirements imposed' under federal law."[64]

Again, Justice O'Connor agreed with Justice Stevens' conclusion that claims specifically alleging the violation of FDA requirements are not preempted.[65] Justice O'Connor explained that "[w]here a state cause of action seeks to enforce [a Food, Drug, and Cosmetic Act] requirement, that claim does not impose a requirement that is 'different from, or in addition to' requirements under federal law."[66] Therefore, majority support existed for the proposition that manufacturing and warning claims that specifically allege the violation of FDA requirements are not precluded.

3. Specificity requirement.—A third conclusion of the Court relates to the question of which claims constitute the imposition of requirements "different from, or in addition to" FDA requirements.[67] Justice Stevens held that in order for a claim to be preempted under section 360k, the potentially preemptive FDA requirements must "be 'applicable to the device' in question" and must either constitute "specific counterpart regulations" or be "'specific' to a 'particular device.'"[68]

---

62. *See Medtronic*, 116 S. Ct. at 2257.

63. The Court specifically looked to 21 C.F.R. § 808.1(d)(2) (1995), which states that section 360k "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." *Medtronic*, 116 S. Ct. at 2256.

64. *Medtronic*, 116 S. Ct. at 2240.

65. *See id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

66. *Id.* Justice O'Connor concluded that "§ 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*." *Id.*

67. *Id.* at 2255-56.

68. *Id.* at 2257. This portion of Justice Stevens' opinion was joined by Justice Breyer, but, while Justice Stevens believed that the specificity requirement would result in "few" cases of MDA preemption, Justice Breyer was not "convinced" that this would be the case. *See id.* at 2262 (Breyer, J., concurring in part and concurring in the judgment).

Justice O'Connor took a broader view of the preemptive capabilities of section 360k.[69] Justice O'Connor discarded Justice Stevens' requirement of constituting "specific counterpart regulations" and argued that state law claims should be preempted if they will "impose 'any requirement' 'which is different from or in addition to,' any requirement applicable to the device under the [MDA]."[70] Justice O'Connor concluded that FDA manufacturing and labeling requirements did exist with respect to Lohr's pacemaker, and, therefore, any state common law claims constituted "additional requirements."[71] Thus, according to Justice O'Connor, Lohr's defective manufacture and labeling claims should have been preempted.[72]

Ultimately, however, Justice Stevens' plurality opinion requiring either "specific counterpart regulations" or regulations relating to the "particular device" was controlling in deciding the outcome of *Medtronic*. Additionally, with the primarily concurring opinion of Justice Breyer, Justice Stevens' opinion regarding what constitutes an "additional requirement" for purposes of 360k preemption appears to have precedential value.

In summary, the Supreme Court's decision in *Medtronic* provides guidance regarding the treatment of medical device products liability claims in three ways. First, state common law design defect claims arising from section 510(k)-approved medical devices are not preempted by section 360k of the MDA.[73] Second, manufacturing and warning claims alleging violation of FDA requirements are not preempted by section 360k.[74] Third, section 360k of the MDA only preempts state tort claims when a claim has the effect of constituting a "specific counterpart regulation" for a device, or is "particular" to a device in question.[75] *Medtronic* does not provide instruction regarding questions of what actually constitutes "specific counterpart regulations" however, nor does the Court agree as to the likely frequency of such occurrences.

---

69. *See Medtronic*, 116 S. Ct. at 2264 (O'Connor, J., concurring in part and dissenting in part).

70. *Id.*

71. *Id.*

72. *See id.* at 2264.

73. *See id.* at 2253-55.

74. *See Medtronic*, 116 S. Ct. at 2256.

75. *Id.* at 2257.

V. Post-*Medtronic* State of Medical Device Products Liability Preemption in Pennsylvania

The decision of the Supreme Court in *Medtronic* has changed the face of MDA preemption for Pennsylvania courts in several ways. First, the trend among Pennsylvania federal courts preempting common law tort claims against products approved through the section 510(k) "substantial equivalence" test has been discontinued.[76] Second, Pennsylvania courts may not find as preempted manufacturing and warning claims that specifically allege violation of FDA requirements.[77] Additionally, Pennsylvania courts must allow all common law tort claims that are not both (1) "'applicable to the device' in question" and (2) either constitute "specific counterpart regulations" or are "'specific' to a 'particular device.'"[78]

The Supreme Court of Pennsylvania's decision in *Green v. Dolsky*[79] provides a good example of the effects of *Medtronic* on preemption in Pennsylvania when compared with the Superior Court of Pennsylvania's pre-*Medtronic* resolution of the same case.[80] *Green* involved a plaintiff who was alleged to have developed an autoimmune disorder after receiving an injection of Zyderm Collagent Implant ("Zyderm") from her physician.[81] Zyderm is a Class III medical device under the MDA that received its approval from the FDA through the standard PMA process.[82] Green brought numerous claims against the manufacturer of Zyderm; all of which were found by the superior court to be preempted by section 360k.[83]

While the Supreme Court of Pennsylvania's post-*Medtronic* consideration of Green's claims resulted in a finding that some of the claims constituted specific counterpart regulations and were,

---

76. *See* English v. Mentor, 67 F.3d 477 (3d Cir. 1995); *In re* Orthopedic Bone Screw Prods. Liab. Litig., No. MDL1014, 1996 WL 221784, at *1 (E.D. Pa. Apr. 8, 1996).

77. *See supra* notes 62-66 and accompanying text.

78. *See supra* notes 67-72 and accompanying text.

79. 685 A.2d 110 (Pa. 1996).

80. *See* Green v. Dolsky, 641 A.2d 600 (Pa. Super. Ct. 1994).

81. *See Green*, 685 A.2d at 113.

82. *See id.*

83. *See Green*, 641 A.2d at 605-07. The claims were based on theories of negligence, strict liability, breach of warranty, and fraud in obtaining FDA approval to market Zyderm. *See id.* at 601.

consequently, preempted by section 360k,[84] the court found that several of Green's claims were not preempted by section 360k because they, "in essence, mirror[ed] FDA requirements . . . ."[85]

While *Green* provides an example of the application of the "specific counterpart regulations" preemption test in Pennsylvania, it is possible that the courts of other states will differ on their handling of the matter. This may result in forcing both device manufacturers and recipients to cater to a broad range of liability patterns.

Medtronic has also had an impact on the subject matter jurisdiction of federal courts within Pennsylvania. This impact was recognized in August 1996 by the United States District Court for the Eastern District of Pennsylvania in *Falcone v. Baxter*.[86] In *Falcone*, the court remanded a medical devices suit to Pennsylvania state court for lack of subject matter jurisdiction. The *Falcone* court came to the conclusion that a majority of the *Medtronic* Court, through the opinions of Justices Stevens and Breyer, agreed that "Congress had never intended the MDA to preempt . . . garden-variety tort claims . . . , at least in the absence of

---

84. *See Green*, 685 A.2d at 117. The claims that the court found preempted by section 360k were: negligent development of the product; failing to warn plaintiff; failing to give adequate warning to physicians; failing to properly label the product; and Green's strict liability claim. *See id.* at 117-18. With respect to the failure to warn claims, the court noted that the FDA had specifically approved the labeling and package inserts including the Physician Package Insert. *See id.* at 117, nn.5-6.

85. *Id.* at 117-18. The claims found not preempted by the court were: negligent distribution of Zyderm in commerce knowing Zyderm to be defective and dangerous; allowing Zyderm to be sold in the face of known consequences; failing to test adequately in the face of known consequences; failing to provide the FDA with all data; failing to provide the FDA with known product risks and reactions; failing to adequately study adverse reaction in the face of known consequences; allowing Zyderm to be sold while knowing of dangerous propensities; providing the FDA with false fraudulent and incomplete testing results; providing the FDA with false, fraudulent, and incomplete adverse reaction or injury information; failing to withdraw Zyderm from the market under the circumstances; and failing to properly monitor and identify patients who had been injected with Zyderm after learning of the adverse consequences, to the extent that post-approval studies were required of Collagen by the FDA. *See id.*

The *Green* court also found that Green's claims of "being negligent as a matter of law; being otherwise negligent, careless, or reckless; and violating the statutes, laws or regulations of the United States and Pennsylvania" were too general for the court to make a proper preemption determination. *Id.* at 117.

86. No. Civ.A.96-2943, 1996 WL 482981, at *1 (E.D. Pa. Aug. 23, 1993). *See also* Headen v. Mentor, No. Civ.A.96-1459, 1997 WL 27104, at *1 (E.D. Pa. Jan. 23, 1997) (remanding a medical device products liability action to Pennsylvania state court for lack of subject matter jurisdiction).

a specific indication from the Food and Drug Administration to the contrary."[87] And, as a result, the *Falcone* court found that it lacked subject matter jurisdiction to hear the case.

VI. Effects of *Medtronic*'s Preemption Limitations on Consumers, Manufacturers, and Providers

A. Effects on Consumers

The *Medtronic* decision affects medical device consumers in several ways. First, the limitation of manufacturers' ability to use MDA preemption provides incentive for manufacturers to produce safer products. Second, the products liability suits allowed as a result of the *Medtronic* decision will serve to spread the costs of injuries resulting from defective medical devices among device consumers. Of course, it must be noted that a spreading of costs, by its own terms, promises to result in an increase in the retail costs of medical devices. Third, *Medtronic* serves to reopen an avenue of relief for injured device recipients that has not been available for many recipients in recent years.

1. Preemption limitation provides manufacturers with incentive to produce safer products.—With respect to section 510(k)-approved devices, the enhanced potential liability resulting from *Medtronic* presents device manufacturers with the choice of either designing and manufacturing safer products or compensating injured plaintiffs.[88] Because liability often outweighs costs saved by manufacturers in producing inferior products, manufacturers are economically encouraged to design and manufacture safer products.[89]

With respect to devices receiving FDA approval through the standard PMA process, *Medtronic* provides extra incentive for

---

87. *Falcone*, 1996 WL 482981, at *2.

88. *See* William R. Hadley, *Strict Liability—The Medical Malpractice Citadel Still Stands*, 11 CREIGHTON L. REV. 1357, 1360 (1978); Laura K. Jortberg, *Who Should Bear the Burden of Experimental Medical Device Testing: The Preemptive Scope of the Medical Device Amendments Under* Slater v. Optical Radiation Corp., 43 DEPAUL L. REV. 963, 982 (1994).

89. M. Kristen Rand, counsel on behalf of Consumers Union, explained to the Senate Government Affairs Committee that "[c]ivil liability for manufacturing and marketing dangerously defective medical devices provides an irreplaceable incentive in making medical devices safer and in ensuring that consumers who are injured by defective devices are compensated." Statement Before Senate Comm. on Regulation and Governmental Affairs, 103d Cong. (1994), *available in* 1994 WL 233511.

device manufacturers to strictly comply with and document all phases of the PMA process for new devices. The additional pressure of civil litigation will help ensure that FDA regulations and procedures will be followed, thereby enabling future device recipients to be more confident of the quality of new devices.

2. Spread the costs of defective medical devices.—A second reason that the *Medtronic* decision is important to medical device consumers is that enhanced potential liability will help spread the costs of defective medical devices among device consumers.[90] When manufacturers are held liable for injuries caused by defective devices, the resulting costs are eventually incorporated into the prices of their products and are thereby passed on to other medical device consumers.[91] The passing on of litigation costs to subsequent consumers is justified by the fact that subsequent consumers are the recipients of safer devices.[92] Additionally, device consumers, as potential recipients of defective devices, have an interest in allowing manufacturer liability for defective devices.[93]

3. Reopens an avenue of relief for victims of defective devices.—Another reason *Medtronic* is important for medical device recipients is because, in *Medtronic*, the Court reopened an avenue of relief for device recipients. The *Medtronic* Court recognized that the FDA premarket approval requirements, particularly those outlined by section 510(k), were not sufficient to protect device consumers from falling victim to defective devices. In so doing, the Court also helped quell the shock waves attributable to its prior decision in *Cipollone*[94] that had the effect of denying recovery for victims of medical device defects.[95]

---

90. *See* Jortberg, *supra* note 88, at 983.

91. *See generally* William C. Powers, Jr., *Distinguishing Between Products and Services in Strict Liability*, 62 N.C. L. REV. 415, 423-28 (1984).

92. Jortberg explains that "[l]oss spreading is justified in part by the fact that future consumers benefit from information gathered during the period prior to their own use of the product." Jortberg, *supra* note 88, at 983.

93. In his concurring opinion in *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436 (Cal. 1944), Judge Roger Traynor explained, regarding the seriousness of being the victim of a defective product: "The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business." *Id.* at 441.

94. Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).

95. It should be noted that the effect of denying preemption for medical products liability suits, especially those against manufacturers of products approved through the sec-

Following are several examples that illustrate the inherent problems resulting from a broad application of MDA preemption to Class III medical devices. Some of the following examples also demonstrate how the Supreme Court's ruling in *Medtronic* has resulted in eventual relief for some victims and their families.

a. Mini-Profile catheter.—The "Mini-Profile" heart catheter was a product designed and manufactured by C.R. Bard, Inc.[96] for use in angioplasty procedures.[97] The catheter consisted of a four and a half foot long tube about one eighth of an inch thick with a tiny balloon at one end.[98] Angioplasty procedures consist of inserting the tube, with the balloon deflated, through an opening in a vein in the arm or groin and threading the tube through the body to the arteries near the heart.[99] Once the balloon is in position, it is temporarily inflated to compact any plaque building up within the artery.[100] The balloon is then deflated, and the tube is removed from the patient's body.[101]

No later than February 1988, executives at C.R. Bard became aware that the Mini-Profile catheter did not always deflate properly.[102] C.R. Bard executives were also aware that failure to deflate could cause death.[103] Regardless of such information,

---

tion 510(k) process, has the potential to greatly impact the number of actionable claims in the field of medical devices products liability. Since the enactment of the MDA in 1976, section 510(k) notification has become the dominant means of receiving FDA premarket approval. In 1990, it was reported that section 510(k) notifications accounted for 99 percent of new Class III devices entering the market, and 80 percent of all medical device submissions (includes Class I and Class II medical devices). *See* H.R. REP. NO. 101-808, at 14 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6307 (testimony of FDA Commissioner David A. Kessler before the Senate Comm. on Labor and Human Resources, Apr. 6, 1995). These statistics suggest that even though the decision in *Medtronic* may not have a major impact on states which, prior to *Medtronic*, did not recognize preemption for section 510(k)-approved devices, states previously holding otherwise, such as Pennsylvania, may be dramatically impacted.

96. Around 400,000 angioplasties are performed each year, making angioplasty a $900 million industry. Between 1980 and 1985, C.R. Bard held a virtual monopoly on the production of angioplasty catheters, but by 1988 its share of the market was cut in half. *See* Mitchell Zuckoff & John H. Kennedy, *Heart Catheter Became Killer: Mass.-Made Unit Blamed in Fraud,* BOSTON GLOBE, Oct. 31, 1993, at 1.

97. *See* Brief Amici Curiae of American Association of Retired Persons at 10, Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996) (Nos. 95-754, 95-886).

98. *See* Zuckoff & Kennedy, *supra* note 96, at 1.

99. *See id.*

100. *See id.*

101. *See id.*

102. *See id.*

103. *See* Zuckoff & Kennedy, *supra* note 96, at 1.

C.R. Bard filed an inaccurate statement in support of its application with the FDA pursuant to the section 510(k) premarket approval process.[104] In May 1988, the FDA granted approval of the Mini-Profile catheter.[105] Between July and November of that year, C.R. Bard received at least twenty-eight complaints from doctors and others about the catheter's failure to deflate.[106] C.R. Bard continued to ship the catheter while secretly making modifications in an attempt to rectify the problem.[107]

In November 1988, Eunice Beavers suffered a mild heart attack.[108] Beavers' cardiologist recommended a balloon angioplasty in order to clear out any blockages that were impeding blood flow to her heart.[109] Beavers' daughters recalled being assured that the odds against a problem were "1,000 to 1."[110] On December 28, 1988, Eunice Beavers died.[111] Beavers' cardiologist, Dr. John Cox, explained that after inserting the catheter into the clogged coronary artery and inflating the balloon, "the device did not deflate as it was supposed to."[112] Beavers died shortly thereafter.

Eventually, the FDA was informed of C.R. Bard's misconduct from one of C.R. Bard's competitors and began to investigate the competitor's allegations.[113] The investigation resulted in C.R. Bard pleading guilty to 391 counts of conspiracy, mail fraud, lying to regulators, and shipping "adulterated products" for human experimentation.[114] Accordingly, C.R. Bard was fined sixty one

---

104. *See id.*

105. *See* Brief Amici Curiae of American Association of Retired Persons at 10, Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996) (Nos. 95-754, 95-886).

106. *See id.*

107. *See id.* According to FDA Commissioner David Kessler, C.R. Bard was essentially "using unsuspecting patients as guinea pigs and operating rooms as laboratories for unapproved products." Zuckoff & Kennedy, *supra* note 96, at 2.

108. *See* Zuckoff & Kennedy, *supra* note 96, at 1.

109. *See id.*

110. *Id.*

111. *See id.*

112. *Id.*

113. *See* Brief Amici Curiae of American Association of Retired Persons at 10, Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996) (Nos. 95-754, 95-886).

114. *See* Zuckoff & Kennedy, *supra* note 96, at 1. The charges alleged that C.R. Bard had also hidden from the FDA knowledge that the tip of a separate catheter, called the B Probe, tended to break off inside patients. *See id.* Fifty patients actually had the tip break off inside them during surgery causing, in some cases, excruciating prolonged pain and permanent disablement. *See* Brief Amici Curiae of American Association of Retired Persons at 10, *Medtronic* (Nos. 95-754, 95-886).

million dollars.[115] Further, three individual C.R. Bard executives were each sentenced to eighteen months in prison for making false statements to the FDA concerning the reliability of the heart catheters.[116]

When the Beavers family, along with other victims of the defective catheters, sought restitution in the criminal proceedings against C.R. Bard in April 1994, they were informed by United States District Judge Mark L. Wolf that civil suits were a more appropriate means of redressing injuries because pain and suffering and punitive damages might be available.[117] Ironically, four months later, Judge Wolf dismissed the Beavers' civil suit holding that their claims were preempted by section 360k of the MDA.[118] Judge Wolf's decision was affirmed by the First Circuit Court of Appeals; the Beavers family filed a petition for certiorari on February 16, 1996.[119]

The Beavers family and C.R. Bard eventually reached a confidential out-of-court settlement in the same month that the Supreme Court decided *Medtronic*.[120] It appears likely that the *Medtronic* decision was the catalyst for the eventual compensation of the family of Eunice Beavers.

b. Bjork-Shiley heart valve.—A second example of the insufficiency of the FDA regulations imposed pursuant to the MDA in protecting medical device consumers involves the Bjork-Shiley heart valve. The Bjork-Shiley heart valve is a mechanical heart valve that is used to replace diseased or deformed valves. It received its FDA approval under the section 510(k) process in April 1979 despite the fact that during clinical trials one of the valves had fractured.[121] In fact, the FDA's Los Angeles District

---

115. *See id.*

116. *See* Jennifer B. Lee, *Ex-Bard Executives Sentenced: Three Given 18 Months in Heart Catheter Case,* BOSTON GLOBE, Aug. 9, 1996, at 1.

117. *See* United States v. C.R. Bard, Inc., 848 F. Supp. 287, 292-93 (D. Mass. 1994).

118. *See* Talbot v. C.R. Bard, Inc., 865 F. Supp. 37, 45 (D. Mass. 1994).

119. *See* Talbot v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed,* (U.S. Feb. 6, 1996) (No. 95-1321).

120. *See* Lee, *supra* note 116, at 1.

121. *See* Brief Amici Curiae of American Association of Retired Persons at 21, Medtronic Inc. v. Lohr, 116 S. Ct. 2240 (1996) (Nos. 95-754, 95-886); HOUSE COMM. ON ENERGY AND COMMERCE, SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, 103D CONG., 1ST SESS., A REPORT: LESS THAN THE SUM OF ITS PARTS: REFORMS NEEDED IN THE ORGANIZATION, MANAGEMENT, AND RESOURCES OF THE FOOD AND DRUG ADMINISTRATION'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH 22 (Comm. Print 103-N

Office warned the FDA Headquarters in that same year about the "frequency of catastrophic failures" with the heart valve.[122] No action was taken by the FDA in response to the Los Angeles District Office's warnings.[123]

In January 1984, the FDA, despite confirmation of seventy-three fractures causing fifty-eight deaths, decided not to recall the heart valves at that time, but, instead, requested additional data regarding the therapeutic value of the valve.[124] Interestingly, the additional data was not even requested for purposes of evaluating the safety of the valve.[125] FDA officials later explained that the agency did not recall the valve pursuant to its apparent authority under the MDA because the MDA procedure was "so lengthy and difficult to sustain in court that it [had] never been used."[126]

In the fall of 1985, after the FDA was made aware that a major television network had planned to air a segment on the heart valve issue, the FDA scheduled a panel hearing to evaluate the safety of the Bjork-Shiley heart valve.[127] In 1986, prior to the panel hearing, Shiley removed the valve from the market.[128] By the time Shiley removed the valve from the market, approximately forty thousand patients had received the valves.[129] At that time, there were at least 186 reported heart valve fractures.[130] By the end of January 1993, the total number of fractures Shiley valves had reached 501.[131]

Prior to *Cipollone* in 1992, civil litigation provided a source of compensation for some victims including those benefitting from a class action settlement against Shiley, Inc. and its corporate parent, Pfizer, Inc.[132] However, since *Cipollone*, Shiley has successfully

---

1993) [hereinafter LESS THAN THE SUM].

122. LESS THAN THE SUM, *supra* note 121, at 22.

123. *See id.*

124. *See id.* at 22, 28.

125. *See id.* at 22.

126. *Id.* at 5.

127. *See* LESS THAN THE SUM, *supra* note 121, at 5.

128. *See id.*

129. *See* STAFF OF SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, COMM. ON ENERGY AND COMMERCE, 101ST CONG., 2D SESS., THE BJORK-SHILEY HEART VALVE: "EARN AS YOU LEARN"; SHILEY INC.'S BREACH OF THE HONOR SYSTEM AND FDA'S FAILURE IN MEDICAL DEVICE REGULATION 2 (Comm. Print 101-R 1990).

130. *See* LESS THAN THE SUM, *supra* note 121, at 22.

131. *See id.* at 32.

132. *See* Bowling v. Pfizer, Inc., 143 F.R.D. 141 (S.D. Ohio 1992).

asserted that claims regarding manufacturing and warning defects are preempted by the MDA.[133]

c. Vitek jaw implant.—The Vitek Jaw Implant further illustrates the insufficiency of the section 510(k) process as a means of insuring quality medical devices. In the 1960s, the Dow Corning Corporation began marketing a silicone jaw implant for patients suffering from temporomandibular joint disorder ("TMJ"), a painful condition that can result in muscle spasms, misaligned teeth, arthritis, and other injury.[134] Between five hundred thousand to one million Americans seek treatment for TMJ each year. Eighty to ninety percent of those seeking treatment are women.[135]

In 1983, the FDA approved, through the section 510(k) substantial equivalency process, a Teflon jaw implant manufactured by Vitek.[136] The jaw implant was manufactured using a specific type of Teflon, called Proplast, that had never been tested in either animals or humans prior to its release on the market.[137] Shortly after the jaw implant became available on the market, evidence began to suggest that the devices were susceptible to fragmentation causing debilitating pain and permanent skull deterioration.[138] Between 1983 and 1990 over 26,000 patients had received the implants.[139]

Interestingly, civil litigation caused Vitek to withdraw its jaw implant in 1988, two years prior to the issuance of an FDA safety alert.[140] Ultimately, it was civil litigation and not the FDA that was responsible for the removal of Proplast jaw implants from the market. Had lawsuits against Vitek begun in 1993, after *Cipollone* and before *Medtronic*, it seems likely that holdings of MDA preemption through section 360k would have sheltered Vitek in many jurisdictions. This would have allowed Vitek to continue

---

133. *See* Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir. 1995), *cert. denied*, 116 S. Ct. 67 (1995).

134. *See* Judy Foreman, *Danger Cited in Teflon Jaw Implants,* BOSTON GLOBE, June 5, 1992, at 11.

135. *See id.*

136. *See id.*

137. *See id.*

138. *See id.* At a congressional hearing on June 4, 1992, Dr. Daniel Laskin, editor of the Journal of Oral and Maxillofacial Surgery, testified that as early as 1986, doctors were aware of patients suffering tissue inflammation, bone decay, "intense pain," and "jaw dysfunction" from the implants. *See id.*

139. *See* Foreman, *supra* note 134, at 11.

140. *See id.*

marketing the Proplast jaw implants until the FDA intervened at some unknown time in the future.

d. Pedicle screws.—The presently on-going product liability suits involving pedicle screws provide a final example demonstrating the critical role that civil litigation plays as a means of promoting the safe design, manufacture, and labeling of medical devices. Pedicle screws are bone screws that are used in spinal fusion operations.[141] The screws are implanted between narrow archways in the spine called pedicles and serve as foundations for attaching metal plates to the patients' vertebrae.[142] In 1986, the FDA approved the use of bone screws in long bones like arms and legs through the section 510(k) procedure, but twice refused, in 1984 and 1985, to approve their use in spinal fusion operations because of the screws' close proximity to the spinal canal and nerve roots.[143]

Notwithstanding the FDA's refusals to authorize spinal use, manufacturers began to promote the screws for general use in the spine.[144] At present, three thousand plaintiffs are suing pedicle screw manufacturers for injuries ranging from intense chronic pain and numbness in the legs to sexual dysfunction caused by the screws shifting and breaking.[145]

Manufacturers suggest that the FDA's section 510(k) approval of arm and leg uses for the screws was a tacit approval of "off-label" use of the screws in spine operations.[146] According to William W. Vodra, the FDA's associate chief counsel for drugs from 1974 to 1979, off-label use by doctors is "extraordinarily common."[147] Vodra further claims that the "FDA generally does not try to regulate [off-label use] unless it poses a major public health problem."[148]

---

141. *See* Claudia MacLachlan, *Bone Screw Suit Places FDA in a 4-way Squeeze: Agency's Limited Approval of Medical Device Lets Makers Sell for Wider Uses,* NAT'L L.J., Jan. 8, 1996, at A1.

142. *See id.*

143. *See id.*

144. *See* Brief Amici Curiae of American Association of Retired Persons at 26, Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996) (Nos. 95-754, 95-886).

145. *See* MacLachlan, *supra* note 141, at A1.

146. *See id.* As explained by MacLachan, "[o]ff label use refers to the practice of using a product approved for one application in another." *Id.*

147. *Id.*

148. *Id.*

Apparently, the FDA agrees with the assertions of the pedicle screw manufacturers that the FDA had given its tacit approval of the use of pedicle screws. The FDA has proposed to reclassify pedicle screws from Class III devices to Class II devices and has also granted clearance for the marketing of some pedicle screws for use in spinal fusion operations.[149] This proposed change in the FDA's treatment of pedicle screws has been fraught with allegations that manufacturers falsified data and marketed the screws for use prior to any animal or human testing; that surgeons promoted the use of pedicle screws while receiving stock options from screw manufacturers; and that the FDA relied on studies authored by some of these same surgeons.[150] Additionally, at the advice of legal counsel, a number of the documents associated with the FDA's latest pedicle screw clinical study were destroyed by the research institution compiling the clinical data for the study.[151]

In spite of the disturbing allegations presented in the legal action against the manufacturers of the screws, the federal district court hearing the case has determined that all claims, with the exception of express warranty and unlawful promotion claims, were preempted by section 360k of the MDA.[152]

B. Impact on the Medical Devices Industry

Despite the apparent inadequacy of the FDA's efforts to regulate the medical devices industry using the MDA, device manufacturers suggest that allowing victims to recover under state tort claims unduly stifles the development and marketing of medical devices. Accordingly, the argument follows, when civil suits are not preempted, manufacturers opt against spending time and resources developing new medical devices due to fear of civil liability.[153]

---

149. *See id.*

150. *See* MacLachlan, *supra* note 141, at A1.

151. *See* Brief Amici Curiae of American Association of Retired Persons at 26-27, Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996) (Nos. 95-754, 95-886).

152. *In re* Orthopedic Bone Screw Prods. Liab. Litig., No. MDL1014, 1996 WL 221784, at *1 (E.D. Pa. Apr. 8, 1996). The court's holding on the matter was made with prejudice, recognizing that *Medtronic* was presently being reviewed by the United States Supreme Court. *See id.* at *7.

153. *See, e.g., Health Care Liability Reform and Quality Assurance Act of 1995: Hearings on S. 454 Before the Senate Comm. on Labor and Human Resources,* 104th Cong. 38 (1995) (statement of Thomas Scully, President and CEO of the Federation of American Health Systems); *Entrepreneurship in America; Loosening the Government Noose on Small Business,*

While product liability suits impose significant costs on medical device manufacturers, according to some sources, these costs are often overstated by manufacturers for purposes of retaining immunity from products liability actions. For instance, one recent study claims that in 1993 product liability costs represented a mere 19.9¢ per one hundred dollars of retail sales.[154] Another recent study conducted jointly by The Risk and Insurance Management Society and Tillinghast-Towers Perrin, surveying 729 large companies, showed that in 1994 the total "cost of risk," including the companies' costs in buying insurance and paying for uninsured losses resulting from accidents, natural disasters, crime, and lawsuits, was $7.30 per one thousand dollars of revenue.[155] Further, the fact that medical device manufacturers have profited from a degree of immunity in recent years does not mean that such immunity was ever intended by Congress or should be permitted to continue.

One particular area of concern expressed by medical device manufacturers relates to biomaterials suppliers withdrawing particular biomaterials from the medical device market due to liability exposure concerns.[156] Polyester, silicone, Teflon, and polyurethane are all examples of biomaterials whose manufacturers have limited or ceased production due to concerns regarding litigation. It is notable, however, that most courts considering the issue of bulk supplier liability to device recipients have held suppliers liable only where the suppliers were aware of how the materials buyers intended to use the products and knew the risks associated with the intended uses.[157]

Field Hearing Before the Senate Comm. on Small Business, 104th Cong. 111 (1995) (statement of E.R. Pickard, Chairman and CEO, Sofamor Danek Group, Inc.); *Product Liability: Hearing Before the Subcomm. on Technology and Competitiveness of the House Comm. on Science, Space, and Technology,* 102d Cong. 115 (1992) (statement of Dane Miller, Ph.D., President and CEO of Biomet, Inc.).

154. *See The Cost of Liability Insurance to American Business: Hearings Before the Subcomm. on Administrative Oversight and the Courts,* 104th Cong. (1995), *available in* 1995 WL 253269 (testimony of J. Robert Hunter, Director of Insurance Consumer Federation of America).

155. Ellen E. Schultz, *Large Employers Are Carrying Lighter Loads of Liability Costs,* WALL ST. J., Dec. 12, 1995, at B5.

156. *See* James S. Benson, *Biomaterials,* MED. DEVICE & DIAGNOSTIC INDUS., Apr. 1995, at 34.

157. *See* Frederick D. Baker, *Effects of Products Liability on Bulk Suppliers of Biomaterials,* 50 FOOD & DRUG L.J. 455 (1995).

C. *Effects on Providers*

Presumably, the decision in *Medtronic* should provide a degree of relief to medical services providers. In jurisdictions that prior to *Medtronic*, favored the preemption of product liability claims against manufacturers, plaintiffs often looked to hospitals and physicians for damages. Allowance of such claims to be brought against device manufacturers will likely cause plaintiffs to focus on deeper-pocketed manufacturers to satisfy their claims. At a minimum, providers will not be the only contributors compensating victims of defective or deficient medical devices.

D. *Proposed FDA Creation and Enforcement of Detailed Regulations for Specific Devices*

Perhaps the most workable solution for device manufacturers following *Medtronic* would be for the FDA to create and enforce detailed regulations for as many specific devices as would be feasible.[158] Such regulations would be beneficial for device manufacturers because they would give device manufacturers a standard on which they could reasonably rely throughout the United States. Manufacturers would not be compelled to predict how each court would interpret the term "specific counter-part regulations" and then tailor their products to the lowest common denominator for liability purposes. Instead, manufacturers could accurately predict at the research and development stage whether or not a specific product would be too costly to justify further research or production.

State and federal courts would also benefit from explicit FDA regulations specific to particular devices because such regulations would lessen the number of cases in which courts would need to make judgments in gray areas regarding which tort claims constitute "specific counter-part regulations." The benefits of specific regulations would also enable plaintiffs to rely on the regulations to provide the components of their claims. Finally, the creation of specific regulations would be an important step in fulfilling the original intent of Congress in enacting the MDA.[159]

---

158. On November 22, 1993, the FDA proposed to stiffen the design standards for medical devices. *See* 56 Fed. Reg. 61,952 (1993); *see also FDA Seeks to Stiffen Rule on Medical Devices,* N.Y. TIMES, Nov. 21, 1993, at 28.

159. *See supra* notes 3-5 and accompanying text.

Of course, Congress would have to be willing to provide the FDA with additional funding for both the creation of device-specific regulations and more rigorous premarket testing. However, if the original purpose of the MDA in providing safe and effective medical devices is still a congressional priority, funding should be granted.

VII. Conclusion

The Supreme Court's decision in *Medtronic, Inc. v. Lohr* provides a critical step in turning away from the dangerous course chosen by many courts following *Cipollone* using the MDA, a set of amendments created to enhance the safety and effectiveness of medical devices, as a means of sheltering medical device manufacturers from liability. While the *Medtronic* Court is somewhat obscure regarding which claims actually constitute "specific counterpart regulations" sufficient to trigger MDA preemption, the Court does provide that claims against section 510(k)-approved devices and claims alleging violation of FDA regulations are not preempted. Additionally, *Medtronic* leaves the door open for the FDA to create additional specific requirements for medical devices and thereby provide the means by which the MDA could better achieve their intended purpose of providing consumers with safe, effective medical devices.

Kenneth J. Witzel